IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AVENTIS PHARMA S.A., SANOFI-AVENTIS U.S., LLC Plaintiffs, v. HOSPIRA, INC., APOTEX, INC., and APOTEX CORP., Defendant.	Civil Action No. 07-721-GMS (Consolidated) **PUBLIC VERSION**

HOSPIRA'S SECOND MOTION IN LIMINE TO PRECLUDE SANOFI'S EXPERTS FROM TESTIFYING ABOUT THE CLAIM CONSTRUCTION OF "PERFUSION"

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Richard K. Herrmann #405
Mary B. Matterer #2696
MORRIS JAMES LLP
500 Delaware Avenue, Suite 1500
Wilmington, DE 19801-1494
(302) 888-6800
rherrmann@morrisjames.com

James F. Hurst
Imron T. Aly
WINSTON & STRAWN LLP
35 West Wacker Drive
Chicago, IL 60601
(312) 558-5600

Attorneys for Defendant
HOSPIRA, INC.

INTRODUCTION

The Court has already construed the disputed claim terms, and the time for further construction is over. Nonetheless, to attempt to fit the claims to Sanofi's new arguments, Sanofi's experts have made it clear they intend to testify about the proper construction of the term "perfusion." Sanofi is belatedly attempting to saddle that single word with "extra baggage" based on new arguments that another District Court already rejected in *Medeva Pharmaceuticals Mfg., Inc. v. Morton Grove Pharms.*, 174 F.Supp.2d 802 (N.D.Ill. 2001). Permitting Sanofi's experts to testify about claim construction issues would invade the province of the Court and contradict settled Federal Circuit law about claim construction.

BACKGROUND

Sanofi's experts also seek to distort the meaning of "perfusion." During claim construction proceedings, the parties originally disputed the meaning of the term "perfusion" as used in claim 5 of the '561 patent. To help limit the number of issues presented to the Court, the parties agreed to a construction of the term as used in that claim. According to the stipulated construction, a perfusion is "a solution suitable for infusion into patients including at least active pharmaceutical ingredient and an aqueous infusion fluid such as physiological saline or glucose." (D.I. 44, Joint Claim Construction Chart, at 3.)

This is consistent with the asserted '561 patent, which describes that perfusions are injectable solutions that are made by diluting stock solutions. (Ex. 1, '561 patent, at col. 1, ll. 40-49; col. 2, ll. 23-36.) The Court has construed "stock solution" to mean "a concentrated solution." (D.I. 153, Order, at 1.) When these stock solutions are diluted, such as by adding them to an IV bag, they are called perfusions.

Now, in the course of their reports and deposition testimony, Sanofi's experts seek to add additional limitations to the word "perfusion" that the parties never remotely agreed to saddle

onto that single word. [redacted]

For instance, when Sanofi distinguished the Tarr prior art reference during patent prosecution, Sanofi referred to the Tarr "perfusions (diluted solutions)" even though Sanofi argued that the Tarr perfusions were unstable. (Ex. 4, Prosecution History.) [redacted] Thus, Sanofi's experts should not be allowed to add multiple amorphous limitations to the simple word "perfusion."

ARGUMENT

I. Claim Construction Is A Matter Of Law For The Court

It is black letter law that claim construction is "exclusively within the province of the

Court." *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 391 (1996); *see also Genzyme Corp. v. Atrium Med. Corp.*, 212 F. Supp. 2d 292, 300 (D. Del. 2002) (same). In this case, the Court has already construed the disputed claim terms.

II. Sanofi's Experts Should Not Change Or Add To The Claim Terms

Sanofi should be precluded from adding new limitations to the term "perfusion," particularly because Sanofi's new claim-construction arguments are not just far too late, but they have also been squarely and correctly rejected under indistinguishable circumstances. *See Medeva Pharmaceuticals Mfg.*, 174 F.Supp.2d 802 (N.D.Ill. 2001).

This Court construed a stock solution as a "concentrated" solution of the drug. A perfusion is nothing more than the next step, the solution you get when you dilute the stock solution to get it ready for administration to the patient. That is exactly what the parties agreed to as a definition for "perfusion:" "a solution suitable for infusion into patients including at least active pharmaceutical ingredient and an aqueous infusion fluid such as physiological saline or glucose." (D.I. 44, Joint Claim Construction Chart, at 3.)

This definition was simply intended to express the plain and ordinary meaning of an "infusion," which is part of the agreed definition and the word the National Cancer Institute itself defines as follows: "a method of putting fluids, including drugs, into the bloodstream. Also called intravenous infusion." (Ex. 5, NCI Dictionary, at 17.) The agreed construction used the phrase "suitable for infusion into patients" to distinguish an infusion from other pharmaceutical forms like tablets, capsules, or trans-dermal patches.

[redacted]

[redacted] It is far too late now to add such detailed limitations to the simple word "perfusion."

The new proposed limitations also are clearly incorrect and far too amorphous to add anything to the proper analysis. The district court in *Medeva Pharmaceuticals* considered and rejected the same kinds of limitations when construing the phrase "suitable for oral administration." Just like here, the patentee in that case argued that "suitable for oral administration" contemplates "patient acceptance, stability, toxicity and efficacy." *Medeva Pharms.*, 174 F. Supp.2d at 806. The Court rejected that argument for all the same reasons the argument should be rejected here, noting that the phrase was "too cryptic and too inartful" to convey to any "objective reader the congeries of meanings now sought to be attributed to that phrase." *Id.* The court further explained that:

> Drugs are routinely administered orally despite their being unstable, horrid-tasting, highly toxic and without therapeutic activity. For example, solutions made extemporaneously by pharmacists and used in a very short period of time need not be stable, yet they may be "suitable for oral administration" Similarly, Morton Grove has pointed to various drugs that are administered orally yet are horrid tasting.

Id. Thus, the Court rejected the proposed limitations because the patentee was putting "extra baggage" and "more weight onto the phrase 'suitable for oral administration' than it can possibly carry," further explaining that the effort was nothing more than a "hindsight revaluation of what its patent counsel should perhaps have said if the intention were indeed to convey the multiple considerations it now seeks to advance." *Id.* As a result, the district court construed the term simply as meaning that "animals and/or humans can ingest the solution orally" without leading to "certain death or debilitating harm or, perhaps, contain[ing] ingredients humans are incapable of digesting and eliminating." *Id.* at 805-806.

[redacted]

[redacted]

These and other properties of perfusions may relate to what makes a product commercially viable and a "successful product." *Id.* at 806. But that has nothing to do with whether it is a "perfusion" as used in the asserted patent. A perfusion is the way of injecting a formulation to a patient, and nothing more is required. Sanofi's experts should not be allowed to testify at trial that a perfusion must meet additional limitations, such as any threshold safety or stability, because these features are not part of what makes a perfusion a perfusion.

CONCLUSION

For the above reasons, the Court should preclude Plaintiffs from adding changing or adding to the claim constructions that have already been established in this case.

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By: */s/ Richard K. Herrmann*

Richard K. Herrmann #405
Mary B. Matterer #2696
MORRIS JAMES LLP
500 Delaware Avenue, Suite 1500
Wilmington, DE 19801-1494
(302) 888-6800
rherrmann@morrisjames.com

James F. Hurst
Imron T. Aly
WINSTON & STRAWN LLP
35 West Wacker Drive
Chicago, IL 60601
(312) 558-5600
jhurst@winston.com
ialy@winston.com
Attorneys for Defendant HOSPIRA, INC.